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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,993

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EXAMINER

ORWIG, KEVIN S

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

11/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/587,993		ADDISON ET AL.	
	Examiner		Art Unit	
	Kevin S. Orwig		1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep. 26, 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/31/06, 8/2/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Claims 1-9 are currently pending. Claims 1-8 are the subject of this Office Action. This is the first Office Action on the merits of the claims. Non-elected claim 9 is withdrawn from consideration.

Election/Restrictions

Applicants' election of Group II (claims 1-8) in the reply filed on Sep. 26, 2008 is acknowledged. In response to applicant's election, Group I (claim 9) is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicants have elected Group II with traverse.

The traversal is on the ground(s) that a search of both Groups I and II together would not impose a serious burden. This traversal is not found to be persuasive because there are two inventions, one drawn to a product (a polyurethane foam) and one drawn to a method. Group I is drawn to a different statutory category of invention (a composition of matter) than Group II which is drawn to a methods. While related by a polyurethane foam, the two inventions are not so closely related as to depend absolutely upon one another and are therefore patentably distinct.

The MPEP 808.02 states that a serious search burden may be established by showing that a different field of search must be employed to search for one of the inventions in a manner not likely to result in art pertinent to the other invention(s). The

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invention of Group II is drawn to a polyurethane foam obtainable by the process of claim 6. The methods of claims 2-5, 7, and 8 are therefore independent of the foam of Group I. As such, a search of the two groups would not be coextensive and prior art for the methods of 2-5, 7, and 8 may not be prior art for the polyurethane foam of claim 9. Thus, the restriction requirement is still deemed proper and is therefore made FINAL.

Priority

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be Feb. 2, 2005, the filing date of PCT application PCT/GB05/00359 to which the instant national stage 371 application claims priority. Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the British application was filed with the USPTO on Jul. 31, 2006.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEONG (U.S. 6,326,410; Issued Dec. 4, 2001) (hereinafter Cheong; 2nd Reference on IDS dated Aug. 2, 2007) in view of WEBSTER (U.S. 4,664,662; Issued May, 12, 1987) (hereinafter Webster).

1. Cheong discloses polyurethane foams useful as wound dressings and methods to make the same (abstract; column 5, lines 15-36). Cheong teaches a method of forming the polyurethane foam comprising mixing 1 part by weight of an isocyanate-capped prepolymer having from 0.5 to 1.2 meq NCO groups/gm with 0.509 to 1.18 parts by weight of water in the presence of from 0.05 to 0.4 parts by weight of a C1 to C3 monohydric alcohol (column 5, lines 18-23; claims 1-2). Cheong also teaches drying the foamed product (column 5, lines 25-27). Cheong does not explicitly teach treating the foamed product with a dispersion of therapeutic agent prior to drying.

2. However, Cheong contemplates such treatment by teaching that "the foams of the invention may also include topical medicaments and antiseptics...as well as other therapeutically useful additives." Furthermore, treatment of similar polyurethane foams with therapeutic agents is well-known in the art. For example, Webster teaches polyurethane foam wound dressings that may contain therapeutic agents (abstract; column 7, line 61 to column 8, line 7; claim 11). Webster teaches that the

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physiologically active component may be incorporated into the foam prior to use by soaking (i.e. treating) it in a solution of the components (column 8, lines 8-13).

3. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to treat the polyurethane foams of Cheong with a dispersion of a therapeutic agent, then drying the treated product as taught by Cheong, to provide a wound dressing material comprising a therapeutically active agent, reading on claim 1. One would have been motivated to do so since both Cheong and Webster teach that it is useful to include such agents on polyurethane wound dressing materials, as would be clear to the ordinary artisan. Therefore if an artisan wanted to produce a medicated foam dressing material, one would have been motivated to treat the polyurethane foams of Cheong with a dispersion of a therapeutic agent per the teachings of Webster.

4. Regarding claim 2, Cheong teaches that methanol is a particularly preferred monohydric alcohol for use in the method of forming the foams (column 3, lines 42-48), reading on claim 2.

5. Regarding claim 3, Cheong teaches that the prepolymer of the invention is preferably an isocyanate-capped polyether such as an ethyleneoxy/propyleneoxy copolymer (column 2, lines 44-48), reading on instant claims 3 and 4.

6. Regarding claim 5, Cheong teaches a method of forming the polyurethane foam comprising mixing 1 part by weight of an isocyanate-capped prepolymer having from 0.5 to 1.2 meq NCO groups/gm with 0.509 to 1.18 parts by weight of water (column 5, lines

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18-23; claim 1). Additionally, Cheong teaches mixing the isocyanate-capped prepolymer with 0.6 to 0.9 parts by weight of water (claim 7), reading on claim 5.

7. Regarding claim 6, Cheong teaches a method of forming the polyurethane foam comprising mixing 1 part by weight of an isocyanate-capped prepolymer having from 0.5 to 1.2 meq NCO groups/gm with 0.6 to parts by weight of water in the presence of from 0.6 to 0.4 parts by weight of a C1 to C3 monohydric alcohol (column 5, lines 18-23; claims 1-2). Additionally, Cheong teaches mixing these components in the presence of from 0.1 to 0.25 parts by weight of methanol or from 0.1 to 0.3 parts by weight of ethanol (claims 8 and 9), reading on claim 6.

8. Regarding claim 7, Cheong teaches drying the polyurethane foam product (column 5, lines 25-27) as discussed above. Cheong does not explicitly teach treating the foamed product with a dispersion of therapeutic agent prior to drying, and thus does not teach an extra drying step.

9. However, as discussed above Webster teaches that physiologically active components may be incorporated into the foam prior to use by soaking (i.e. treating) it in a solution of the components (column 8, lines 8-13). Webster teaches that the physiologically active component may be incorporated just prior to use (column 8, lines 8-13). Webster also teaches drying the foam in an oven. For instance, Example 1 demonstrates the preparation of a polyurethane dressing material that is not treated with an active agent. Thus, one of ordinary skill in the art would recognize that the foams of Webster would have been dried prior to soaking them in a solution of the active agent(s). Webster teaches soaking the dried foam in a solution of an active

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agent followed by drying (column 8, lines 13-17). Therefore, in combination with Cheong, Webster teaches the method to make the foams of instant claim 6 including the step of drying the foam prior to treatment with an active agent. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to dry the polyurethane foams again after soaking the foam in a solution of the active agent as taught by Webster. The ordinary artisan would have been motivated to do so since the artisan would readily envisage advantages of drying the foam after such treatment, for example for long-term storage and ease of packaging the foams/wound dressings. Thus, the combined teachings of Cheong and Webster read on claim 7.

10. Regarding claim 8, Webster teaches that the foams may be treated with a 5% w/v solution of chlorhexidine gluconate (column 8, lines 13-17). The ordinary artisan would recognize that this solution is an aqueous solution since Webster teaches that this soaking treatment is preferred for those physiologically active components that are soluble in water (column 8, lines 11-13), and chlorhexidine gluconate is water soluble. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to treat the polyurethane foams of Cheong with an aqueous solution of agent having a concentration of from 1 to 20% wt per the teachings of Webster, reading on claim 8. The ordinary artisan would have had a reasonable expectation of success in doing so since Cheong suggests such a treatment as discussed above, and since Webster exemplifies such a treatment with an active agent in this concentration range.

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A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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KSO

/Andrew D Kosar/
Primary Examiner, Art Unit 1654